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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,800	01/12/2006	Mark Bride	65793-5009	5126

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,800

Applicant(s)

BRIDE, MARK

Examiner

Helene Bor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/30/2006 & 8/30/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Preliminary Amendments

1. For the record, acknowledgement is made of the applicant's preliminary amendments to the claims under 37 CFR 1.115. It is acknowledged that applicant added claims, 2-10. Under examination are the newly amended claims, 1-10.

Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).**
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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3. The disclosure is objected to because of the following informalities: Missing a Brief Description of the Drawings.

Appropriate correction is required.

4. Claim 2 is objected to because of the following informalities:

a. Page 3, First Line ~ liht is misspelled; --light--

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1-2, 5-8 & 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lui'334 et al (US Patent No. 6021344).

Claim 1: Lui'334 teaches the method of screening epithelial tissue for possible abnormal tissue sites (Abstract). Lui'334 teaches the method of illuminating a gross anatomical area or epithelial tissue [diseased site] with a light of preselected wavelengths that selectively aids in visualizing abnormal tissue sites on the gross area (Col. 2, Line 21-25). Lui'334 teaches the method of viewing said gross area through filter lens which transmit light in the preselected wavelengths (Col. 4, Line 40-44). In addition, Lui'334 teaches while substantially blocking transmission of light of wavelengths other than the preselected wavelengths, to enhance the visualization of

any of the abnormal tissue sites (Col. 4, Line 44-48) in the presence of normal ambient light [visible light which is also called excitation light] (Col. 3, Line 20-28).

Claim 2: Lui'334 teaches the method of detecting abnormal epithelial tissue (Abstract). Lui'334 teaches the method of illuminating an area of epithelial tissue with light having at least one preselected wavelength such that the light is reflected from the area and thereby creating reflected light (Col. 2, Line 21-28). Lui'334 teaches the method of filtering the reflected light to substantially remove wavelengths other than the at least one preselected wavelength, thereby creating filtered light (Col. 4, Line 40-44). Lui'334 teaches the method of viewing the filtered light (Col. 3, Line 56-60).

Claim 5/2: Lui'334 teaches the method wherein the at least one preselected wavelength is from about 400 nm to about 600 nm (Col. 3, Line 20-28).

Claim 6/2: Lui'334 teaches the method wherein the abnormal epithelial tissue includes tumor phenotypes (Col. 6, Line 7-35).

Claim 7/2: Lui'334 teaches the method wherein the light further comprises ambient light [visible light/excitation light] and the step of filtering substantially removes ambient light (Col. 4, Line 40-44).

Claim 10/2: Lui'334 teaches the method further comprising providing spectacles (Figure 2, Element 4) having a filter (Figure 2 Element 6 & 7), and wherein the step of filtering the reflected light comprises filtering the reflected light with the spectacles (Col. 3, Line 56-60).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 3-4 & 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lui'334 et al (US Patent No. 6021344) as applied to claim 1-2, 5-7 & 10 above, and further in view of Lonkey'983 (US Patent No. 5,329,938).

Claim 3/2: Lui'334 fails to teach the light being white. However, Lonkey'983 teaches various anomalies which show white light (Col. 8, Line 22-50). It would have been obvious to one of ordinary skill in the art to combine the teachings of Lui'334 and Lonkey'983 in order to provide a more accurate detection of problems in the region to be examined (Col. 8, Line 20-21).

Claim 4/3/2: Lui'334 teaches, wherein the method based on the filtered light, performing an assessment of the area, wherein the assessment is one selected from the group consisting of a tissue biopsy, a histological analysis, or a molecular analysis

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(Col. 6, Line 36-39 & Col. 1, Line 17-28). Lui'334 fails to teach the light being white. However, Lonkey'983 teaches various anomalies which show white light (Col. 8, Line 22-50). It would have been obvious to one of ordinary skill in the art to combine the teachings of Lui'334 and Lonkey'983 in order to provide a more accurate detection of problems in the region to be examined (Col. 8, Line 20-21).

Claim 8/2: Lui'334 fails to teach the method wherein the illuminating is from a chemiluminescent light. However, Lonkey'983 teaches the illuminating step comprises directing light emitted from a chemiluminescent light source toward the area of epithelial tissue (Col. 5, Line 25-33). It would have been obvious to one of ordinary skill in the art to combine the teachings of Lui'334 and Lonkey'983 in order to take advantage of a shadowless and more economical illumination source (Col. 4, Line 25-33).

Claim 9/2: Lui'334 fails to teach the method with the first, second and third wavelength. However, Lonkey'983 teaches a method wherein at least one preselected wavelength comprising a first wavelength of about 450 nm, a second wavelength of about 550 nm, and a third wavelength of about 600 nm (Col. 4, Line 48-52). It would have been obvious to one of ordinary skill in the art to combine the teachings of Lui'334 and Lonkey'983 in order emanate or elicit white light (Col. 4, Line 48-52).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- b. Banerjee, Bhaskar. Detection of cancer using cellular autofluorescence, 03/20/2003. US 20030055341 A1.

c. Mycek, Mary-Ann et al. Fluorescence lifetime spectrometer (fls) and methods of detecting diseased tissues, 04/15/2004. US 20040073119 A1.


d. Palcic, Branko et al. Endoscopic imaging system for diseased tissue, 04/16/1996. US 5507287 A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER